

PTO/SB/21 (09-04)

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Total Number of Pages in This Submission

	Application Number	10/712,546
	Filing Date	November 12, 2003
	First Named Inventor	Joseph S. Podolski
	Art Unit	1614
	Examiner Name	
8	Attorney Docket Number	07189.0028.CPUS02

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Howrey Simon Arnold & White, LLP		
Signature			
Printed name	Teddy C. Scott, Jr., Ph.D.		
Date	October 15, 2004	Reg. No.	53,573

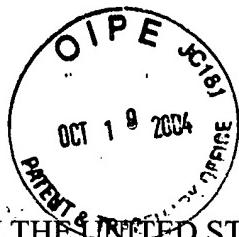
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Typed or printed name	Teddy C. Scott, Jr., Ph.D.	Date	October 15, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT
Attorney Docket No. 07189.0028.CPSU02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Joseph S. Podolski
App. No.: 10/712,546
Filing Date: November 12, 2003
Title: METHODS AND COMPOSITIONS
WITH TRANS-CLOMIPHENE FOR
TREATING WASTING AND
LIPODYSTROPHY
Art Unit: 1614

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

10/15/04

Date

Teddy C. Scott

Registration No. 53,573

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§ 1.56, 1.97 and 1.98**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.97 and the continuing duty of disclosure under 37 C.F.R. § 1.56, Applicants call to the attention of the Examiner the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. It is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Forms PTO/SB/08A and PTO/SB/08B be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement is not to be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), this Information Disclosure Statement is not to be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This application is a continuation-in-part of International Application

No PCT/US02/21524, filed July 9, 2002, the national stage of which is Application No. 10/483,458 (the "Priority Application"), and is relied upon for an earlier effective filing date under 35 U.S.C. § 120. The documents cited on Forms PTO/SB/08A and PTO/SB/08B were cited and submitted to the Patent and Trademark Office in the Priority Application. In accordance with 37 C.F.R. § 1.98(d), copies of the documents are not provided herewith.

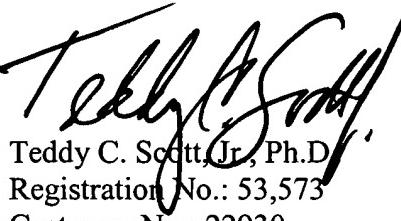
This Information Disclosure Statement is being filed prior to the receipt of a first Office Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b)(3).

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account 08-3038. referencing docket number 07189.0028.CPUS02.

Respectfully submitted,

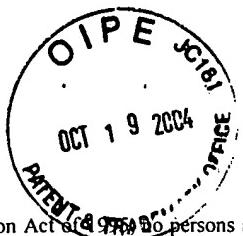
HOWREY SIMON ARNOLD & WHITE, LLP

By:


Teddy C. Scott, Jr., Ph.D.
Registration No.: 53,573
Customer No.: 22930

Dated: October 15, 2004

HOWREY SIMON ARNOLD & WHITE, LLP
321 N. Clark Street, Suite 3400
Chicago, IL 60661
(312) 595-1239 (main)
(312) 846-5621 (direct)
(312) 595-2250 (fax)



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
Sheet	1	of	5	Application Number	10/712,546
				Filing Date	November 12, 2003
				First Named Inventor	Joseph S. Podolski
				Group Art Unit	1614
				Examiner Name	
				Attorney Docket Number	07189.0028.CPUS02

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number – Kind Code ² (if known)			
A1	4,061,733		12/06/1977	Gunjikar	
A2	5,728,688		03/1998	Labrie	
A3	5,861,389		01/1999	Radlmaier	
A4	6,096,338		08/01/2000	Lacy	
A5	6,126,969		10/03/2000	Shah	
A6	6,129,933		10/10/2000	Oshlack	
A7	6,143,353		11/07/2000	Oshlack	
A8	6,190,591		02/23/2001	Van Lengerich	
A9	6,221,399		04/24/2001	Rolfes	
A10	6,248,363 B1		06/19/2001-1	Patel	
A11	6,391,920 B1		05/21/2002	Fisch	
A12	US 2002/0120012 A1		09/29/2002	Fisch	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ – Number ⁴ – Kind Code ⁵ (if known)			
	B1	EP 0888775 A2	07/01/1999	Medical College of Hampton Roads	
	B2	WO 03/005954 A2	01/23/2003	Zonagen, Inc.	
	B3	WO 95/35093	12/28/1995	University of Nebraska Board of Regents	
	B4	JP 4-312522			
	B5	WO 01/91744 A1	12/20/2001	Fisch	

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¹ Applicant's unique citation designation number (optional). ² See Kinds codes of USPTO Patent Documents as www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/712,546
				Filing Date	November 12, 2003
				First Named Inventor	Joseph S. Podolski
				Group Art Unit	1614
				Examiner Name	
Sheet	2		5	Attorney Docket Number	07189.0028.CPUS02

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published		T ²
	C1	Ben-Jonathan, N., et al., "Dopamine as a Prolactin (PRL) Inhibitor," Endocr. Rev. 22(6), pp.724-63 (2001)		
	C2	Breznik, R., et al., "Effectiveness of Antiestrogens in Infertile Men," Arch. Androl., Vol. 31(1), pp. 43-48 (1993)		
	C3	Check, J., et al., "Empirical Therapy of the Male with Clomiphene in Couples with Unexplained Infertility" Int. Journal Fertil., Vol. 34(2), pp. 120-122 (1989)		
	C4	Cooper, A., et al., "The Effects of Clomiphene in Impotence A Clinical and Endocrine Study," British Journal of Psychiatry, Vol. 120, pp. 327-330 (1972)		
	C5	Cunningham, G., et al., "Testosterone Replacement Therapy and Sleep-Related Erections in Hypogonadal Men," J. Clin. Endocrinol. Metab., Vol. 70, No. 3, pp. 792-797 (1990)		
	C6	Dangprasit, P., et al., "Development of Diclofenac Sodium Controlled Release Solid Dispersions by Spray Drying Using Optimization Strategy I. Powder Formulation," Drug. Devel. And Industrial Pharm. 21(20), pp.2323-2337 (1995)		
	C7	Davidson, J., et al., "Effects of Androgen on Sexual Behavior in Hypogonadal Men," J. Clin. Endocrinol. Metab., Vol. 48, No. 6, pp. 955-958 (1979)		
	C8	Ernst, S., et al., "Stereochemistry of Geometric Isomers of Clomiphene: A Correction of the Literature and A Reexamination of Structure-Activity Relationships," J. Pharmaceut. Sci., Vol. 65, pp. 148-150 (1976)		

Examiner Signature	Date Considered
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/712,546
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				First Named Inventor	Joseph S. Podolski
				Group Art Unit	1614
				Examiner Name	
Sheet	3		5	Attorney Docket Number	07189.0028.CPUS02

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published		
	C9	Feldman, H., et al., "Age Trends in the Level of Serum Testosterone and Other Hormones in Middle-Aged Men: Longitudinal Results from the Massachusetts Male Aging Study," J Clin Endocrinol Metab. 87(2), pp.589-598 (2002)		T ²
	C10	Fuse, H., et al., "Changes in Seminal Plasma Transferring Concentration Following Administration of Clomiphene Citrate," Archives of Andrology, Vol. 31, pp. 139-145 (1993)		
	C11	Guay, A., et al., "Effect of Raising Endogenous Testosterone Levels in Impotent Men with Secondary Hypogonadism: Double Blind Placebo-Controlled Trial with Clomiphene Citrate," Journal of Clinical Endocrinology and Metabolism, Vol. 80, No. 12, pp. 3546-3552 (1995)		
	C12	Guay, A., et al., "Possible Hypothalamic Impotence," Urology, Vol. 38, No. 4, pp. 317-322 (1991)		
	C13	Guay A., et al., "Results of Double Blinded Treatment With Clomiphene Citrate In Patients With Hypogoadotropic Hypogonadism," Annual Meeting of the Endocrine Society, Abstract No. 386, (June 1993)		
	C14	Hirshkowitz, M., et al., "Androgen and Sleep-Related Erections," J. Psychosomatic Research, Vol. 42, No. 6, pp. 541-546 (1997)		
	C15	Homonnai, Z., et al., "Clomiphene Citrate Treatment in Oligozoospermia: Comparison Between Two Regimens of Low-Dose Treatment," Fertility And Sterility., Vol. 60, No. 5, pp. 801-804 (1988)		
	C16	Jarow, J., "Nonsurgical Treatment of Male Infertility: Empiric Therapy," Therapy, Chapter 23, pp. 410-422 (date of Publication Not Available)		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/712,546
				Filing Date	November 12, 2003
				First Named Inventor	Joseph S. Podolski
				Group Art Unit	1614
				Examiner Name	
Sheet	4		5	Attorney Docket Number	07189.0028.CPUS02

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published		
	C17	Kharenko, A., et al., "Controlled Release From Oral Formulations Based on Interpolymeric Polymethacrylic Acid – Polyethylene Glycol Complex," Proceed. Intern. Symp. Control Rel. Bioact. Mater., Vol. 22, pp. 232-233 (1995)		T ²
	C18	Matsumoto, A., et al., "Human Chorionic Gonadotropin and Testicular Function: Stimulation of Testosterone, Testosterone Precursors, and Sperm Production Despite High Estradiol Levels," Journal of Clinical Endocrinol. And Metab. Vol. 56, No. 4, pp. 720-728 (1983)		
	C19	Merck Index, 13th Ed., Entry 2410, p. 417 (2001)		
	C20	Meshali, M., et al., "Effect of Interpolymer Complex Formation of Chitosan With Pectin or Acaxia on the Release Behaviour of Chlorpromazine HC1" Int. J. Phar., Vol. 89, pp. 177-181 (1993)		
	C21	Morales, A., et al., "Andropause: A Misnomer For A True Clinical Entity," J. Urol., Vol. 163, No. 3, pp. 705-12 (March 2000) Abstract		
	C22	Purvis, K., et al., "Stability of Sperm Characteristics in Men with Disturbances in Sperm Quality," Int. Journal Androl., 12, pp. 171-178 (1989)		
	C23	Soderguard, R., et al., "Calculation of Free and Bound Fractions of Testosterone and Estradiol-17 β to Human Plasma Proteins at Body Temperature," J. Steroid Biochem, Vol. 16, pp. 801-810 (1982)		
	C24	Sternbach, et al., "Age-associated Testosterone Decline in Men: Clinical Issues for Psychiatry," Am. J. Psychiatry, Vol. 155, No. 10, pp. 1310-8 (1998) Abstract		

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/712,546
			Filing Date	November 12, 2003
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Sheet	5	5	Attorney Docket Number	07189.0028.CPUS02

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
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	C25	Suzuki, et al., "Endocrine Environment of Benign Prostatic Hyperplasia: Prostate Size and Volume are Correlated with Serum Estrogen Concentration," Scand. J. Urol. Nephrol., Vol. 29, No. 1, pp. 65-8 (1995) Abstract	
	C26	Tenover, J., et al., "Serum Bioactive and Immunoreactive Follicle-Stimulating Hormone Levels and the Response to Clomiphene in Healthy Young and Elderly Men," Journal Clinical Endocrinol. And Metab., Vol. 64, No. 6, pp. 1103-1108 (1987)	
	C27	Tenover, J., et al., "The Effects of Aging in Normal Men on Bioavailable Testosterone and Luteinizing Hormone Secretion: Response to Clomiphene Citrate," Journal Clinical Endocrinol. Metab. , Vol. 65, No. 6, pp. 1118-1126 (1987)	
	C28	U.S. Pharmacopeia, United States Phamacopeia, 26 th Ed., pp. 484-485 (2003)	

Examiner Signature	Date Considered
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